DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Refer to: 1171449

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
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02-BLT-18

June 21, 2002

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Kirsten W. Alcorn, MD
Medical Director Transfusion Services
Washington Hospital Center Blood Bank
110 Irving Street, NW
Washington, DC 20010

Dear Dr. Alcorn,

During an inspection of Washington Hospital Center, Blood Bank, located at 110 Irving Street, NW, Washington, DC 20010, on May 6 through 17, 2002, the Food and Drug Administration (FDA) documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.*, and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to maintain complete and accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed (21 CFR § 606.160(e)) in that:

   a. The [redacted] blood bank softwar[redacted] revisio[redacted] as been used exclusively to screen donors since Fall of 2001. The database either failed to contain donor deferral records previously recorded on 3X5 paper cards or the donor deferral records entered were incomplete as follows:

   - Three donors who had been permanently deferred were never entered into the computerized donor deferral database.

   - One donor who had been indefinitely deferred was never entered into the computerized donor deferral database.

   - Two donors with reactive serology results were never entered into the computerized donor deferral database. Additionally, the paper records were also incomplete in that donors' unique identification numbers were not recorded.

- Two donors with multiple reactive serology results were never entered into the computerized donor deferral database.

- One donor was entered into the database but the donor records are incomplete in that serology test results for the 11/19/89 donation were never entered. A subsequent donation on 4/21/91 tested repeatedly reactive for Hepatitis B core antibody (anti-HBc).

- Three donors had reactive viral marker test results for donations prior to exclusive use of the [redacted] software. The donors' names changed (*i.e.*, due to marriage, etc.) but their original names were never documented in the [redacted] computerized deferral database. Two of the three donors subsequently were allogenic donors under their new names.

- 11 donors with a "positive serology" result have never been entered into the computerized donor deferral database

- 22 autologous donors who would have been either permanently or temporarily deferred for health reasons had they been homologous donors, were never entered into the computerized donor deferral database. For example, 15 donors had a history of cancer, 5 donors had histories with regard to potential vCJD exposure, 1 donor had a history regarding Hepatitis, and 1 donor had a history regarding jaundice.

b. The records for donors [redacted] and [redacted] documented that they had visited one of the following countries Guatemala, Bolivia, and/or Brazil which are known to have areas in which malaria is endemic. The procedure entitled "Donor History and Criteria for Acceptance of Blood Donors" dated March 15, 2000, requires a determination as to whether the donor had visited or had been residents of malaria endemic areas through use of Center for Disease Control and other information. The records for the four donors lacked information documenting the areas of the countries in question and the duration of the visits.

c. The "Daily Work Review" procedure requires additional information for a "yes" answer to determine donor suitability. Records for donor [redacted] indicated that the donor had been previously deferred but did not document the reason for that deferral.

2. Failure to maintain and/or follow written standard operating procedures (SOPs) to include all steps to be followed in the collection, processing, storage, and distribution of blood and blood components (21 CFR §§ 211.200, 606.100(b)) in that:

a. The Medical Director did not document approval on the "Donor History Questionnaire" as required by the SOP entitled, "Donor History and Criteria for Acceptance of Blood Donors" dated March 15, 2000, regarding donors with a history or evidence of Viral Hepatitis. For example, the Donor History Questionnaire documented that donor [redacted] had a prior positive test for Hepatitis C, however, the donor was accepted for

donation and there was no documented approval by the Medical Director on the Donor Questionnaire.

b. Four donors who had experienced accidental needle sticks were not deferred for 12 months as required by the "Donor History and Criteria for Acceptance of Blood Donors" procedure dated March 15, 2000. For example, do[redacted] an[redacted]d experienced accidental needle sticks and were deferred for eight weeks not the required 12 months.

3. Failure to maintain complete and accurate records of blood processing (21 CFR § 606.160(b)(2)) in that blood irradiation records were either incomplete or had incorrect and/or conflicting documentation as follows:

- The Unit number for one irradiated unit was not recorded.

- The length of time which four units had been removed from temperature controlled storage was not recorded.

- The records for seven units did not document whether there was a change in the units' expiration dates or the units' new expiration dates.

- The length of time that four units had been removed from temperature controlled storage was recorded as being less than the specified 6.2 minutes required to perform irradiation.

- The total time that two units had been removed from temperature controlled storage was recorded as being 10 minutes. The irradiator can process only one unit at a time. The minimum time in which two units could be irradiated per specification is [redacted] minutes

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge receipt of your FDA-483 response letter dated June 10, 2002. This letter will be made part of the official file.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken and will take to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please also provide any documentation showing that corrections have been achieved.

Your reply should be sent to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Anita Richardson, Director, Compliance Branch. Ms. Richardson may be reached at (410) 779-5412.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Michael H. Covert, President
Washington Hospital Center
MedStar Health, Chief Operating Officer
110 Irving Street, NW
Washington, DC 20010